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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,337	12/11/2003	Harry S. Sowden	MCP0293-DIV	1381
27777	7590	03/21/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER DAVIS, ROBERT B	
			ART UNIT	PAPER NUMBER
			1722	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,337	SOWDEN ET AL.	
	Examiner	Art Unit	
	Robert B. Davis	1722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 10-20 and 52-57 is/are allowed.
- 6) ☒ Claim(s) 8, 9, 40-51 and 58-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/20/06</u> | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are indefinite because each claim is dependent upon canceled claim 7.

Double Patenting

3. Claims 62 and 63 objected to under 37 CFR 1.75 as being a substantial duplicate of claims 59 and 60. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is suggested that claims 62 and 63 should be amended to depend upon claim 61 to avoid this objection.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 58-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 17, 40-44 and 47-58 of copending Application No. 10/743,364 in view of Guo et al (6,623,754: figure and column 8, line 54 to column 9, line 58). The claims of the co-pending application disclose all claimed features except for a supply of powder having a minimum orifice diameter of flowability greater than about 15mm or 25mm. Guo et al disclose a supply of powder having a Flodex™ number of generally 25 or 20 or less, which is connected to an orifice in a tablet die of a tablet-making machine. It would have been obvious to modify apparatus of the co-pending application by using a supply of powder having a Flodex™ number of about 15 or 25 mm as disclosed by Guo et al for the purpose of matching the flow characteristics of the powder with the diameter of the die tooling of the tablet press (see column 9, lines 21-47).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 40, 41, 46, 47, 58, 60, 61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doepel (4,292,017: figures 1, 2 and 4; column 2, lines 1-19 and column 5, line 53 to column 6, line 24) taken together with Guo et al (6,623,754: figure and column 8, line 54 to column 9, line 58).

Doepel teaches a method and an apparatus for forming compressed dosage forms (tablets), the apparatus comprising: a suction source (vacuum pump-column 5, lines 61-63); a die cavity (38) having a first port for placing the die cavity in flow communication with said suction source (top opening of the die) to said die cavity, and a second port for placing the die cavity in flow communication with a supply of powder (bottom opening of the die), whereby the suction source assists said powder in flowing into the die cavity (see column 2, lines 1-9), a filter (116, 118, 119) disposed between the suction source (attached to conduit 120-see column 5, lines 53-67), punches (40,

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42) for compressing the powder in the die cavity so as to form compressed tablets (figure 5); and a powder recovery system for removing excess powder from the filter, which is a source of compressed air upwardly and the purged product is drawn off by vacuum (column 6, lines 10-24). The vacuum source above the filter to collect the purged powder blown out of the filter is being considered a recovery system. The examiner is drawing a clear line between recovery and recycling. Accordingly, claim 15 does not require recycling structure. The die is disposed proximal to the die cavity as described above and shown in figure 4. The reference does not disclose a supply of powder having a Flodex™ number of 15 or 25 mm.

Guo et al disclose a supply of powder having a Flodex™ number of generally 25 or 20 or less, which is connected to an orifice in a tablet die of a tablet-making machine.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Doepel by using a supply of powder having a Flodex™ number of about 15 or 25 mm as disclosed by Guo et al for the purpose of matching the flow characteristics of the powder with the diameter of the die tooling of the tablet press (see column 9, lines 21-47).

9. Claims 43-45, 49-51 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doepel taken together with Guo et al as applied to claims 40, 41, 46 and 47 above, and further in view of Bullock (5,667,158: figures 1 and 2; column 1, lines 16-30; and column 3, lines 31-47).

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The combination of Doepel and Guo et al discloses all claimed features except recycling of the purged material. Doepel does disclose purging of the filter with compressed air into the die.

Bullock et al disclose a reclaim system for use with a pharmaceutical tablet compression machine, comprising: a filter (114) for collecting material dust, a compressed air source (128) to purge dust from the filter and a canister (112) which feeds dust back to a raw material source (C). The reference fulfills a long felt need for reusing raw material collected from the compression molding machine to save material costs.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Doepel by adding a mechanism for recycling collected raw material as disclosed by Bullock et al for the purpose of saving on material costs by collecting discarded material from a compression molding machine.

10. Claims 40, 46, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al (Soviet reference 662370 A: figures 1-3 and the English abstract) taken together with Guo et al.

Belousov et al teach a method and an apparatus for compression molding of dosage forms (tablets), the apparatus comprising: a suction source (vacuum from the abstract attached to hose (16), a die cavity (4) having a first port (bottom opening of the die) for placing the die cavity in flow communication with the suction source (during the filling period-abstract), a second port (top opening of the die) for placing the die cavity in flow communication with a supply of powder, such that the suction source assists

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powder in flowing into the cavity; a filter (19) disposed between the suction source and the second port. With regards to the method claims, the die is isolated from the filter by moving the dies from the filling table to the compression table.

Guo et al disclose a supply of powder having a Flodex™ number of generally 25 or 20 or less, which is connected to an orifice in a tablet die of a tablet-making machine.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Doepel by using a supply of powder having a Flodex™ number of about 15 or 25 mm as disclosed by Guo et al for the purpose of matching the flow characteristics of the powder with the diameter of the die tooling of the tablet press (see column 9, lines 21-47).

11. Claims 42, 48, 59 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al taken together with Guo et al as applied to claims 40 and 46 above, and further in view of Campbell (3,430,532: figures 2-6 and column 2, lines 3-28).

The combination of Belousov et al and Guo et al disclose all claimed features except for the second port being located in a wall of the die wherein the opening is closed upon upward movement of a bottom plunger or the use of a feed shoe which covers a plurality of dies on a die table as it is rotated past the feed shoe.

Campbell discloses a compression molding machine having a die (18) having openings (98) connected to a vacuum source for assisting in the quick, uniform loading of the die and a feed head (84) covering a plurality of dies (18) on a die table (86).

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It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Belousov et al by using a lateral opening of the die connected to a vacuum source for assisting in filling of the die as disclosed by Campbell for the purpose of assuring uniform filling of the plurality of dies. It would have been further obvious to modify the apparatus of Belousov et al by using a feed head that covers a plurality of dies on a die table as disclosed by Campbell for the purpose of feeding particulate material to a plurality of dies.

Allowable Subject Matter

12. Claims 1-6, 11-20 and 52-57 are allowed over the prior art of record.
13. The following is a statement of reasons for the indication of allowable subject matter: In regards to claim 13, the claim is being interpreted as requiring a supply of powder having a minimum orifice diameter of flowability greater than about 30 mm as measured by the FlodexTM test. The amendment to the supply of powder in the amendment of 1/4/07 makes it clear that the supply of powder and not merely being connected to a supply of powder is required by the claim.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

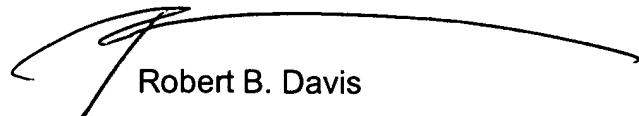
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert B. Davis

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Primary Examiner
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